



**[Billing Code 4140-01-P]**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Prospective Grant of Exclusive Patent License:** Use of pharmaceutical and biological compositions comprising Gram-negative bacteria for the topical treatment of dermatological diseases and dermatological conditions.

**AGENCY:** National Institutes of Health

**ACTION:** Notice.

**SUMMARY:** The National Institute of Allergy and Infectious Diseases, an institute of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an Exclusive Commercialization Patent License to practice the inventions embodied in the Patents and Patent Applications listed in the Summary Information section of this notice to Forte Biosciences, Inc. located in San Diego, California.

**DATES:** Only written comments and/or applications for a license which are received by the National Institute of Allergy and Infectious Diseases' Technology Transfer and Intellectual Property Office on or before [INSERT DATE 15 DAYS FROM DATE OF PUBLICATION OF NOTICE IN THE FEDERAL REGISTER] will be considered.

**ADDRESSES:** Requests for copies of the patent application, inquiries, and comments relating to the contemplated Exclusive Commercialization Patent License should be directed to: David Yang, Technology Transfer and Patenting Specialist, Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Suite 6D, Rockville, MD

20852-9804; Email: yangp3@nih.gov; Telephone: (240) 627-3413; Facsimile: (240) 627-3117.

## **SUPPLEMENTARY INFORMATION:**

### **Intellectual Property**

US Provisional Application 62/324,762, filed April 19, 2016, and PCT Patent Application PCT/US2017/028133, filed April 17, 2017, both entitled “Use of Gram Negative Species to Treat Atopic Dermatitis” [HHS Ref. E-099-2016/0], and U.S. and foreign patent applications claiming priority to the aforementioned applications.

The patent rights in these inventions have been assigned to the government of the United States of America.

The prospective exclusive license territory may be worldwide and the field of use may be limited to the following field of use: “Use of pharmaceutical and biological compositions comprising Gram-negative bacteria for the topical treatment of dermatological diseases and dermatological conditions”.

Atopic dermatitis (AD) is a common, recurrent, chronic inflammatory skin disease that is a cause of considerable economic and social burden. It is one of the most prevalent skin disorders, affecting ~25% of children in developed and developing countries and is expected to continue to escalate. This increased rate of incidence has changed the focus of research on AD toward epidemiology, prevention, and treatment.

The subject technology describes pharmaceutical and biological compositions comprising Gram-negative bacteria that can be developed into a topical treatment for atopic dermatitis (AD), as well as methods and kits using these compositions.

NIAID scientists have recently identified probiotic strains of *Roseomonas mucosa* bacteria that were shown to be beneficial in a pre-clinical mouse model of AD. With this

promising data, NIAID launched a phase I/II clinical trial in March 2017 ([link; https://clinicaltrials.gov/ct2/show/ NCT03018275](https://clinicaltrials.gov/ct2/show/NCT03018275)) and preliminary results from this ongoing study show that the technology may be highly effective at treating and reducing the symptoms of atopic dermatitis. If successfully developed, this invention would be the first live biotherapeutic product approved by the FDA for the treatment of AD.

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR Part 404. The prospective exclusive license will be royalty bearing, and the prospective exclusive license may be granted unless within fifteen (15) days from the date of this published notice, the National Institute of Allergy and Infectious Diseases receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR Part 404.

Complete applications for a license in the prospective field of use that are filed in response to this notice will be treated as objections to the grant of the contemplated Exclusive Commercialization Patent License Agreement. Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the *Freedom of Information Act*, 5 U.S.C. 552.

Dated: October 4, 2017

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Suzanne Frisbie  
Deputy Director  
Technology Transfer and Intellectual Property Office  
National Institute of Allergy and Infectious Diseases  
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